OCT 2 7 2011

510(K) SUMMARY: AGFA DX-D 600

Common/Classification Name: Stationary System, 21 CFR 892.1680
Proprietary Name: DX-D 600
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: August 26, 2011
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DX-D 600, a stationary x-ray system that includes previously cleared digital image capture equipment.

B. DEVICE DESCRIPTION

The device is a combination of a conventional x-ray system with digital image capture equipment. The new device is a ceiling mounted tube and operator console with a motorized patient table and/or wall stand. The DX-D 600 uses Agfa's familiar NX workstation with MUSICA^{2}™ image processing and flat panel detectors of the scintillator-photodetector type (Cesium Iodide or Gadolinium Oxysulfide). It is compatible with Agfa's computed radiography systems as well.

Principles of operation and technological characteristics of the new and predicate devices are the same.

C. INTENDED USE

The DX-D 600 system is indicated to make static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts.

Applications can be performed with the patient in the sitting, standing or lying position.

This device is not intended for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D 600 has an Indications For Use statement nearly identical to the statements for the predicate device, Agfa's DX-D 300. Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE		
	AGFA DX-D 600 (NEW DEVICE)	**AGFA DX-D 300 (PREDICATE-K103050)**
Communications	Same as predicate	DICOM
Detector Material	Same as predicate	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CSI) scintillator
Detector Sizes	Same as predicate	43x43 cm (17x17 in) 43x35 cm (14x17 in.)
Active Matrix	Same as predicate	3072x3072 3072x2560
Pixel size	Same as predicate	139 um
Fill factor	Same as predicate	100%
Dynamic Range	Same as predicate	14 bit DR, 12 bit CR
Image processing	Same as predicate	MUSICA^2
Operating system	Same as predicate	Windows XP Pro
Display System	Same as predicate	Standard PC display or separately cleared medical display (e.g. K051901)
Operator Workstation	Same as predicate	Agfa NX with x-ray soft console
Power Supply	Three phase, 50/60 Hz 380/400/415/440/480 v ±10%	230 / 240 v, 50/60 Hz , ±10% Generator: Three phase, 50/60 Hz 380//480 v ±10%
Electrical Safety	Same as predicate	IEC-60601
Performance Standard	Same as predicate	21CFR1020.30
Generators	Choice of four models: 32 - 80 KW	Choice of four models, 50-80 KW
Tubes	Toshiba models: E7252X, E7254X, E7869X, E7884X	Toshiba models: E7254FX, E7869X & E7884X.
Collimation/AEC	Same as predicate	Automatic or manual collimation, integrated Dose Area Product (DAP) meter and automatic exposure control (AEC).

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D 600 is a traditional ceiling mounted x-ray system for patient exposure and digital image capture.

The x-ray system includes one of four 32-80 kW generators and one of four Toshiba x-ray tubes. A patient table and wall stand are available. Tube rotation, height, source-to-image distance and detector rotation are controlled by motors at the ceiling suspension unit. The operator must be present at the unit to enable motion.

Cesium Iodide or Gadolinium Oxysulfide flat panel detectors are used to capture images. Previews on the NX workstation are available to the operator in as little as one second after exposure. MUSICA^{2TM} image processing provides consistent image quality. DICOM connectivity allows images to be directed to the user's PACS system, archive or hard copy printer. The system is also compatible with Agfa computed radiography systems.

F. TESTING

The product has been tested and shown to conform to electronic medical product safety, radiology, and medical imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, plus collateral standard: Electromagnetic compatibility - requirements and tests.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- ACR/NEMA PS3.1-3.18: Digital Imaging and Communications in Medicine (DICOM)
- IEC 60601-1-3: Medical electrical equipment – Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

MANAGEMENT STANDARDS

- ISO 14971 Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

An image quality evaluation has been conducted comparing images from the new device to the predicate. Sample images have been provided.

Performance of the complete system has been validated.

No clinical testing was performed in the development of the DX-D 600.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 27 2011

Agfa Healthcare, N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K112670
Trade/Device Name: DX-D 600
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 17, 2011
Received: October 20, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112670

Device Name: DX-D 600

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD).

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112670

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